

901 E. 233rd Street Carson, California 90745-6204 310/835-8400 Fax 310/835-6615

4225 '99 JUN 21

June 9, 1999

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street SW
Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statements:

Bone Health Complex

Your Life® Calcium + Soy Isoflavones and Vitamin D is an exceptional complex for bone health. A healthful diet with adequate calcium is essential in achieving peak bone mass in children and young adults and maintaining bone health during adulthood. Individuals who do not store enough calcium throughout their lives have an increased risk for developing osteoporosis. Vitamin D assists in the absorption of calcium. Soy isoflavones, a natural plant hormone (phytoestrogen), in conjunction with calcium and vitamin D, provide supplementation that can help your body to retain bone mass.

on the following product:

YourLife® Calcium 500 mg + Soy Isoflavones 15 mg and Vitamin D 200 I.U.

Very truly yours,

Leiner Health Products

Hany Farag, Director of Regulatory Affairs

cc: William Cochran, Manager of Regulatory Affairs

LET 3790